REMARKS

I. Status of the Claims

Claims 1-18 are under consideration, and claims 19-46 are cancelled in view of the Office's restriction. With this Response, no claims are being amended.

II. Double Patenting Rejection

The Examiner has rejected claims 1-18 on the grounds of nonstatutory obviousness-type double-patenting as allegedly unpatentable over claims 1-19 of U.S. Patent No. 6,682,759 (herein, "the '759 patent"). The Examiner states, in part, that "[t]he '759 patent claims are drawn an identical process save for the ratio of first to second drug [sic]. There is essentially no difference between the instant claims and the '759 patent." Applicants respectfully disagree for the following reason.

Claims 1-19 of the '759 patent are directed to a method for the manufacture of a tablet. The method as claimed in the '759 patent comprises dispersing a second drug in a solid matrix to form a unitary core, depositing on the surface of the unitary core an aqueous suspension of particles of a first drug, and evaporating water from the aqueous suspension to leave a solid shell encasing the unitary core and containing the first drug.

In contrast, the claims of the instant application are directed to a method to manufacture a tablet that has a different configuration than the tablet produced by the method in the '759 patent. In the claimed method, a polymer film devoid of drug is deposited on the drug-containing solid matrix (step (b) of claim 1), and then a fluid with a drug is deposited over the polymer film to form a solid layer of drug on the polymer film (steps (c) and (d) of claim 1).

In determining whether a nonstatutory basis exists for a double patenting rejection, the first question to be asked is - does any claim in the application define merely an invention that is merely an obvious variation of an invention claimed in the patent?. M.P.E.P. 804 II.B.1. Here, the question is whether the method as claimed is an obvious variation of the method claimed in the '759 patent. To arrive at the claimed invention from the method disclosed in the '759 patent, a skilled artisan must additionally include claim 19, step (b): "depositing on a surface of said unitary body a polymeric film that is devoid of either said first drug or said second drug, said polymeric film formed from a polymer effective to prevent interaction of the second

drug and the first drug prior to administration of the dosage form, which dissolves in gastrointestinal fluid upon ingestion." There is nothing in the claims of the '759 patent that show or suggest this additional step, and absent the instant claims, there is nothing in the claims of the '759 patent that suggest such a step to a skilled artisan. Therefore, the claimed method is not an obvious variation of the claims as set forth in the '759 patent. Applicants respectfully request withdrawal of the double-patenting rejection.

III. Rejections Under 35 U.S.C. § 103(a)

Claims 1-18 were rejected as allegedly obvious in view of Johnson *et al.* (U.S. 6,171,618, hereafter "the '618 patent").

A. The Pending Claims.

Applicants respectfully note that the Examiner appears to have mischaracterized the pending claims in the Office Action mailed July 7, 2009. Specifically, in point 6. on page 4 of the Office Action, the Examiner states:

> "The claims are drawn to a method of making a pharmaceutical dosage form comprising depositing a first drug onto a matrix, depositing successive layers of controlled releasing polymers and a second drug onto the matrix, followed by driving off any solvents used."

Pending claim 1 is directed to a method for the manufacture of an oral dosage form which releases a first drug by immediate release and a second drug by prolonged release, and recites, in part,

(a) "dispersing said second drug in a solid matrix to form a unitary body which upon immersion in a gastrointestinal fluid releases said second drug by prolonged release."

(b) "depositing on a surface of said unitary body a polymeric film that is devoid of either said first drug or said second drug, said polymeric film...dissolves in gastrointestinal fluid upon ingestion."

(c) "depositing over said polymeric film a fluid medium comprising said first drug..."

(d) "evaporating said liquid carrier from said fluid medium...to leave a solid layer containing said first drug over said unitary body."

A careful reading of the claim instructs that the polymeric film deposited on the unitary body is one that "dissolves in gastrointestinal fluid upon ingestion", and that step (c) is directed to depositing a drug to leave a solid layer of drug on the dosage form.

B. The Cited Art

The '618 patent is directed to a dosage form comprising cetirizine and pseudoephedrine, containing both a sustained release and an immediate release component. In one embodiment, the sustained released is achieved via use of a semipermeable membrane.

C. Analysis

To establish a *prima facie* case of obviousness, three basic criteria must be met. The third criterion is that the prior art references (or references when combined) must teach or suggest all the claim limitations.

According to the M.P.E.P. § 2143.01 Section V., "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."

C1. The '618 patent does not teach or suggest all claim limitations

As noted above, the Examiner has interpreted the claims as being directed to a method of making a dosage form comprising depositing a first drug onto a matrix, depositing successive layers of controlled releasing polymers and a second drug onto the matrix, followed by driving off any solvents used.

Applicants note that the instantly claimed method comprises, in part, depositing on a surface of the unitary body formed by dispersing the second drug in a solid matrix, a polymeric film that is devoid of either the first or second drug, and which dissolves in gastrointestinal fluid upon ingestion.

In contrast, the dosage form taught in the '618 patent, in one embodiment, comprises a semi-permeable membrane which functions to regulate release of the drug from the core. Accordingly, this semi-permeable membrane does not dissolve

in the gastrointestinal fluid. Rather, as stated in column 10 of the '618 patent, "When the dosage form is ingested..., these water soluble membrane additives are leached out of the membrane, leaving pores which facilitate release of the drug."

The Examiner stated, on page 6 of the Office Action mailed July 7, 2009, that "Since the polyvinyl alcohol of the instant claims results in a membrane being dissolved in the gastrointestinal tract it follows that the polyvinyl alcohol membrane of the '618 patent would dissolve as well." This is technically incorrect.

Polymers such as those taught by the present specification and by the cited reference, are well known in the art for the diverse structural and functional properties they may impart on the compositions that contain them. Such properties are routinely modified through variation of, for example, the amounts and molecular weights of a given polymer present in the composition. One of skill in the art would know under what conditions (i.e., amounts, molecular weight, presence of other components), a particular polymer would, for example, form a water-insoluble membrane or form a membrane which dissolves immediately upon exposure to fluid. Polyvinyl alcohol, is taught in the '618 patent in column 9, lines 9-25, as a polymer to be used in making a rate-limiting membrane which surrounds an immediate release composition. One of skill in the art, when making a rate limiting membrane, would incorporate a polyvinyl alcohol polymer of an appropriate molecular weight, degree of cross-linking, etc. in order to provide a membrane that does not dissolve upon exposure to gastrointestinal fluid. In contrast, polyvinyl alcohol used to form the dissolvable film of the instant claims would be of a molecular weight, degree of cross-linking, etc. to provide a film that dissolves upon exposure to gastrointestinal fluid.

Accordingly, it is the Applicants' position that the polymeric film which dissolves in gastrointestinal fluid upon ingestion, is not taught or suggested by the '618 patent and therefore a *prima facie* case of obviousness has not been established.

C2. Proposed modification would render the dosage form of the '618 patent unsatisfactory for its intended function.

It is the Applicants' position that modifying the dosage form described in the '618 patent by putting a drug-free barrier layer which dissolves in gastrointestinal fluid upon ingestion, around the drug-containing core of the '618 dosage form, would render the '618 dosage form inoperable for its intended purpose, as explained more

fully below. Accordingly, Applicants submit that a *prima facie* case of obviousness has not been established.

The presently claimed method is directed to manufacturing a dosage form with a drug-containing unitary core, which when immersed in gastrointestinal fluid, releases the drug by prolonged release. As clearly taught by the specification, the prolonged or sustained release is imparted by the unitary body. Thus, upon ingestion of the dosage form manufactured by the presently claimed method, there is immediate release from the outer immediate-release layer and the intermediate drug-free barrier layer dissolves in the gastrointestinal fluid. After dissolving of this barrier layer, the drug-containing unitary core functions in the absence of any surrounding or rate-limiting membrane to provide prolonged release of the second drug.

The '618 patent teaches a unitary dosage form having a central core which releases pseudoephedrine in a sustained fashion. The unitary dosage form providing sustained release of drug is not surrounded by a membrane which dissolves in gastric fluid. In an alternative dosage form taught by the '618 patent, the pseudoephedrine core can be formed from an immediate release composition which is surrounded by a water insoluble, permeable, rate-limiting membrane that provides for sustained release of pseudoephedrine by limiting the rate at which pseudoephedrine diffuses into the environment of use (see column 4, lines 51-58).

In other words, membranes surrounding the drug-containing core, as taught in the '618 patent, function solely to regulate drug release from the core. This apparently essential function of the '618 patent dosage forms would be lost if the drug-containing core were to be coated with a polymeric film which dissolves in gastrointestinal fluid upon ingestion. For this reason, the '618 patent does not support a *prima facie* case of obviousness.

Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 103(a).

III. Conclusion

Claims 1-18 are believed to satisfy all of the criteria for patentability and are in condition for Allowance. An early indication of the same is therefore kindly requested.

No fees are believed to be due in connection with this Response. However, the Commissioner is authorized to charge any additional fees that may be required, or credit any overpayment, to King & Spalding LLP Deposit Account No. 50-4616.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650)590-1919.

Respectfully submitted,
King & Spalding LLP

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